

8EHQ-1296-13825

Lilly
Eli Lilly and Company

Lilly Corporate Center
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Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460



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Dear Sir/Madam:

Pursuant to Section 8(e) of the Toxic Substances Control Act, Eli Lilly & Company ("Lilly") is submitting the following information regarding an adverse reaction following human ingestion of a TSCA-regulated substance.

Chemical Substance: monensin sodium

CAS Number: 22373-78-0



88970000075

Source of Information: The information in this submittal was reported to Lilly by a foreign affiliate, which learned of the incident from a foreign customer of the affiliate. The foreign customer purchases monensin sodium from the Lilly affiliate, and Lilly manufactures monensin sodium in the United States. Information regarding the incident was reported orally to the affiliate, and neither Lilly nor its affiliate have any first-hand knowledge or documentation regarding the event that is the subject of this submittal.

Reported Adverse Reaction to Ingestion: On September 25, 1996, three employees of the foreign customer each ingested by mouth an unknown quantity of a solution containing monensin sodium. Within a few hours, all three became very ill. The three employees were evaluated by medical staff of the foreign customer. One of the employees experienced general weakness, muscle pain, anorexia and epigastralgia. The second employee experienced nausea, vomiting, diarrhea, anorexia, sweating, epigastralgia, dehydration and muscle pain. The third employee experienced symptoms similar to the second employee, with an additional

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experience of leg paresis. Some or all of these symptoms continued for a few days. All three employees eventually recovered.

These types of reactions to human ingestion of monensin sodium are not surprising. Monensin is a fermentation product in the ionophore class of compounds. The toxicity of monensin sodium has been thoroughly characterized by studies in laboratory animals. The median lethal dose of monensin sodium in rats is 34 mg/kg.

Extent of Risk Posed by Chemical Substance: This incident occurred as a result of highly unusual product misuse. Monensin sodium's only medicinal/consumptive use is in FDA-regulated animal health products. Lilly does not sell or market it for human use in any form, and its product labels warn against human consumption. Lilly is aware of only one other similar incident of human ingestion, for which Lilly also submitted an 8(e) report.

Please contact me if you have any questions regarding this submittal.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark R. Lange", written in a cursive style.

Mark R. Lange
Attorney
(317)-276-0456

Best Available Copy